

## **Remarks**

### **I. Figures**

Applicants thank the Examiner for indication that the figures previously submitted are acceptable.

### **II. Restriction Requirement**

Applicants again confirm their election of restriction Group III, encompassing claims 79-81, 91, 94, 96, 97, 100, 102, 103, 106, 108, 109, 112, 114, 115, 118, 120, 121, 124, and 126.

Applicants maintain that the complete examination of the application would be most expeditiously handled by treating all of the pending claims as a single entity, and that there is no undue burden in search the subject matter of the pending claims in a single application. As Section 803 of the MPEP states, “[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits. . . .” In view of the foregoing, Applicants respectfully request reconsideration of the restriction requirement.

### **III. Claim Objections**

Applicants note the Examiner has maintained the objection to claims 94, 118, and 120, as being dependent claims which would be allowable if rewritten in independent form and the objection to these claims as depending from a rejected base claim. Applicants further note the objection to claims independent 115 and dependent 118 as being substantial duplicates if claim 115 is found allowable. Applicants thank the Examiner for the indication of allowable subject matter and have amended the claims to render these objections moot. Applicants solicit an indication that the claims are in allowable form in the subsequent Office Action.

**IV. Rejection of Claims 1-2 and 10-22 under 35 U.S.C. §112, 1<sup>st</sup> Paragraph: Written Description**

Claims 79-81, 91, 96, 97, 100, 102, 103, 106, 108, 109, 112, 114, 115, 118, 121, 124, and 126 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. The Examiner has maintained this rejection and has further asserted that Applicant's arguments presented in the December 9, 2002 response were not persuasive because "applicants have not provided a representative number of species of any 8-mer fragment having of SEQ ID NO.: 3 that has any possible functional regulatory region such that the nexus between the claimed sequences and the claimed functions has been clearly established...." The Examiner further maintains that "[I]n view of the open comprising language, the claimed fragments are not just drawn to fragments of SEQ ID NO.: 3, but embrace additional sequences, added on to any such fragment of SEQ ID NO.: 3."

Applicants submit that disclosure of "such descriptive means as words, structures, figures, diagrams formulas, etc., that fully set forth the claimed invention" satisfies the written description requirement, and that they have met this burden. *Enzo Biochem*, 296 F.3d at 1329 (quoting from *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997)). Applicants maintain that they have adequately met the written description requirement for genetic material which "requires a precise definition, such as by structure, formula, chemical name, or physical properties" by providing the express sequence of the claimed nucleic acids. *See, Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). Applicants again note that the

disclosure of the specific nucleotide sequence of SEQ ID NO.: 3 not only provides chemical formula information, but also provides the structure of the claimed molecules.<sup>1</sup>

Applicants maintain that the Examiner's allegation that the claims lack written description support because they are drafted in comprising language does not comport with the requirements of 112 first paragraph written description. As discussed above, compliance with 112 first paragraph is met for genetic materials when a precise definition, such as by structure, formula, chemical name, or physical properties is set forth by applicant for a patent. Because the disclosure sets forth the sequence of SEQ ID NO.: 3 and fragments thereof,<sup>2</sup> there is disclosure of the structure and formula of the claimed nucleotides. Moreover, that the disclosed fragments are claimed in the context of other sequences does not lead to a proper rejection based upon the understood use of comprising terminology in patent claims. It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 42 U.S.P.Q.2d 1608 (stating comprising "is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim" and citing *In re Baxter*, 656 F.2d at 686, 210 U.S.P.Q. at 802); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1572 (stating the word "comprising" is well-established, permits inclusion of other moieties (emphasis original)); *see also, Ex parte Davis*, 80 U.S.P.Q. 448, 450 (BPAI 1948). The claimed nucleotide sequences, are neither altered by virtue of their disclosure as a nucleotide sequence in the midst of other

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<sup>1</sup> Applicants submit that the disclosure of a nucleotide sequence implicitly discloses the molecules' structure as an artisan could write down the chemical structure, including the atoms and bonds involved, based upon the disclosed nucleotide sequence.

<sup>2</sup> See page 28, lines 1-8 for example.

nucleotide sequences, nor does their incorporation to a larger sequence alter the fact that a skilled artisan would readily envision adequate written description support for the claimed nucleic acids in the context of a larger construct.

Applicants respectfully maintain that the Examiner, by asserting a requirement to teach specific sequences and structures that correlate with TIGR gene expression, is imposing additional requirements on patentability in excess of those necessary to meet the written description requirement. Applicants maintain that they need not identify and correlate functional regions of the claimed nucleic acids to meet the written description requirement where they have provided "a precise definition, such as by structure [and] formula." *See, Regents of the University of California*, 119 F.3d at 1566, *supra*.<sup>3</sup>

As noted above, in the response to Applicants' arguments filed December 9, 2002, the Examiner asserts that Applicants have not provided a representative number of 8-mer fragments of SEQ ID NO.: 3, and that there is no nexus between the claimed sequences and the claimed functions to permit one of ordinary skill in the art to readily envisage a representative number of species of such fragments.<sup>4</sup> Applicants respectfully disagree, but to facilitate prosecution the rejected claims have been amended to recite nucleotide fragments from about 15 to about 250 nucleotides in length.

In addition to the foregoing, Applicants again respectfully draw the Examiner's attention to MPEP 2163 II. A.3 (a), stating that identifying characteristics of a biomolecule may include a

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<sup>3</sup> Applicants respectfully submit that although not necessary to meet the requirement for written description, the disclosure is replete with a discussion of the transcription factor binding sites that map to the promoter region. For example, the specification starting at page 25 line 29 and extending through at least page 27 discusses upstream motifs by their sequence locations, and the location of transcription start sites is also given (see figure 1E).

<sup>4</sup> Applicants respectfully submit that the Examiner's assertion with regard to claims 91, 96 103, 106, 108, and 115, is improper as these claims are **not** drawn to fragments of SEQ ID NO: 3 that are at least about 8 nucleotides in length.

sequence or a structure, and the discussion therein of *Lockwood v. American Airlines*. *See, Lockwood*, 107 F.3d at 1572 (holding the written description requirement may be satisfied by using such descriptive means as structures or formulas that fully set forth the invention).

Because Applicants have provided sufficient identifying characteristics<sup>5</sup> including “a precise definition, such as by structure [and] formula,” Applicants have met the requirements of 35 U.S.C. § 112 first paragraph<sup>6</sup> and respectfully request the withdrawal of the rejections of record.

**V. Rejection of Claims 79, 100, and 102 under 35 U.S.C. §102, as allegedly being anticipated by Chojkier *et al.* (U.S. 6,075,027).**

Applicants respectfully submit that it is well-established jurisprudence that in order for a reference to anticipate a claimed invention, it must teach exactly what is claimed. *Titanium Metals Corp. v. Banner* 778 F.2d 775, 227 U.S.P.Q.2d 1766 (Fe, Cir. 1987), *cert. denied* 484 U.S. 1007 (1988). Applicants respectfully submit that whatever else Chojkier *et al.* teaches, it does not teach substantially purified nucleic acid comprising a nucleotide sequence selected from the group consisting of fragments of SEQ ID No: 1-3 and 34, where the nucleotide sequence comprises a functional regulatory region. In this regard, Applicants respectfully note that neither the sequence alleged to be taught by Chojkier *et al.* (GGG GAC TTT CCC), nor its complement, appear in the claimed subject matter. In addition to the foregoing, Applicants further submit that the amendments to claims 79 and 97 would also render the rejection over Chojkier *et al.* moot.

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<sup>5</sup> Applicants respectfully submit that although not necessary to meet the requirement for written description, the disclosure is replete with a discussion of the transcription factor binding sites that map to the promoter region. For example, the specification starting at page 25 line 29 and extending through at least page 27 discusses upstream motifs by their sequence locations, and the location of transcription start sites is also given (see figure 1E).

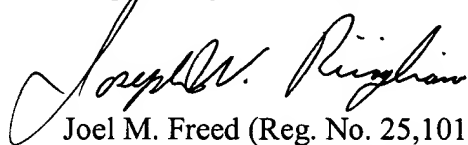
<sup>6</sup> *See, Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991); *Fiers v. Revel* 984 F.2d 1164 (Fed. Cir. 1993); *Fiddles v. Baird*, 30 U.S.P.Q.2d 1481, 1483 (Fed. Cir. 1993); and *Regents of the University of California v. Eli Lilly & Co.* 119 F.3d 1159 (Fed. Cir. 1997).

In view of the foregoing, Applicants submit that the rejection of claims 79, 100, and 102 under 35 U.S.C. § 102(e) is improper and should be withdrawn.

### **Conclusion**

Applicants submit that the claims are in condition for allowance and solicit a notice of allowability at the earliest possible time. Should the Examiner have any questions regarding this application, the Examiner is encouraged to contact Applicant's undersigned representative at 202-942-5174.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Joseph W. Ricigliano". The signature is fluid and cursive, with the first name "Joseph" and last name "Ricigliano" clearly distinguishable.

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